REMARKS

This Amendment is submitted in response to the Office Action dated June 30, 2004. In the Office Action, the Patent Office objected to Claims 1-6, 12 and 13 under 37 CFR §1.75(c) as being of improper dependent form for failing to further limit the subject matter of a previous claim. Further, the Patent Office objected to Claims 1-6, 12 and 13 under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement. Still further, the Patent Office rejected Claims 1-6, 12-14, 21 and 22 under 35 U.S.C. §103(a) as being obvious over *Ginn* (U.S. Patent No. 6,059,802) in view of *Yarger* (U.S. Patent No. 5,360,414).

Applicant notes with appreciation that the Patent Office indicated that Claims 7-11, 15-20, 23, 24 and 26 are allowable.

By the present Amendment, Applicant amended Claims 1-3, 5, 6 and 12. Applicant submits that the amendments to the claims overcome the objections and the rejection by the Patent Office and place the application in condition for allowance. Notice to that effect is respectfully requested.

With respect to the objection of Claims 1-6, 12 and 13 under 37 CFR §1.75(c), the Patent Office asserts:

> Applicant in his claims has referred to a top end, (sic) however such a limitation is no were (sic) in the specification and the examiner has always interpreted the top end to mean the proximal end of the catheter since the bottom end in the specification is referring to the distal end of the catheter 104. However, with the new amendments (sic) it is no (sic) at all clear what the bottom or the top end is referring to. The specification

> refers to a bottom end 104 as shown in figure 2 (sic) the bottom end is the distal end of the catheter 102 (sic) however (sic) the applicant is claiming the bottom end which has a different diameter than the catheter so he must be referring to item 204 in figure 3 and not 104 in figure 2 as indicated by the specification and the drawings. However (sic) that still does not explain what the top end is? (sic)
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> Furthermore, the new amendment refers to a first end and a second end, (sic) besides the fact that such a description does not exists (sic) in the specification and the introduction of such language is deemed new matter, (sic) it is not clear how the first and second end differ from the top and the bottom end.
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> Additionally, the applicant has introduced a first part and a second part of the cylinder which again is NOT in the specification, (sic) however first and second elements are and hence the examiner has interpreted the first and the second end of the cylinder to be the same as the first and second part in the claim.
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> The applicant also claims the second part forms a cross, (sic) however, it is not clear what the cross is referring to since no such thing is in the specification or the drawings, (sic) hence even the introduction of such language is deemed new matter.

As the objection is best understood in view of the grammatical and punctuational errors throughout the objection, Applicant asserts that the objections are improper for the reasons that follow. MPEP §608.01(n) is directed to dependent claims and 37 CFR 1.75 objections and clearly states:

> Any claim which is in dependent form but which is so worded that it, in fact is not, as, for example, it does not include every limitation of the claim on which it depends, will be required to be canceled as not being a proper dependent claim; and cancellation of any further claim depending on such a dependent claim will be similarly required.
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> Where a claim in dependent form is not considered to be a proper dependent claim under 37 CFR 1.75(c), the examiner should object to such claim under 37 CFR 1.75(c) and require cancellation of such improper dependent claim or rewriting of such improper dependent

claim in independent form.

> The test for a proper dependent claim is whether the dependent claim includes every limitation of the parent claim. The test is not whether the claims differ in scope. A proper dependent claim shall not conceivably be infringed by anything which would not also infringe the basic claim.

Claims 1 and 12 are not dependent claims. Moreover, Claims 2, 3 and 5 depend from Claim 1, and Claim 6 depends from Claim 5. Furthermore, dependent Claims 2, 3, 5 and 6 include every limitation of the parent Claim 1. Therefore, Claims 2, 3, 5 and 6 are proper dependent claims according to MPEP §608.01(n). Applicant asserts that the objections to Claims 1-3, 5, 6 and 12 under 37 CFR §1.75(c) were improper and should be withdrawn. Notice to that effect is requested.

With respect to the rejection of Claims 1-6, 12 and 13 under 35 U.S.C. §112, first paragraph, the Patent Office asserts:

> Applicant has amended the claims to read on a first and second end; however, no such description existed in the specification or the original claims. Furthermore, the applicant is also claiming a second and first part where the second part forms a cross. No such description of a first and second part existed in the specification or the original claims, (sic) furthermore (sic) no description of a second part forming a cross existed in the specification or the original claims.

Applicant submits that Claims 1-3, 5, 6 and 12, as amended, only contain subject matter which was described as filed in the specification in such a way as to reasonably convey to one skilled in the relevant art that Applicant, at the time the application was filed, had possession of the claimed invention. Applicant amended

Claims 1-3, 5, 6 and 12 to clarify the claimed invention as described in the specification and illustrated in the drawings of this patent application. Claims 1-3, 5, 6 and 12 were amended to clarify the claimed elements with respect to the specification and the drawings of this patent application and to overcome the objections raised by the Patent Office, as best understood.

More specifically, the "top end" as required by Claims 1-3, 5 and 6 was amended to read the "pointed end" as described in the specification at page 7, line 33. Additionally, the "second end" as required by Claims 1-3, 5 and 6 was amended to read the "blunt end" as described in the specification at page 9, line 14. Further, the "first part" and the "second part" as required by Claims 1-3, 5 and 6 was amended to read the "first element" and the "second element", respectively, as described in the specification at page 9, line 14. Still further, Claim 12, as amended, requires that a flexible hollow body which has the flexible hollow body has a plurality of holes defining passageways to deliver the local aesthetic to the tissue of the patient wherein the passageways extend from an interior of the flexible hollow body to an exterior of the flexible hollow body as described in the specification.

Contrary to the assertions of the Patent Office, MPEP § 2163 states:

> An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully

> set forth the claimed invention. *Lockwood v. American Airlines*, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997). Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention. See, e.g., *Pfaff v. Wells Elecs.*, Inc., 525 U.S. 55, 68, 119 S.Ct. 304, 312, 48 USPQ2d 1641, 1647 (1998); *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406; *Amgen, Inc. v. Chugai Pharmaceutical*, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991).

Independent Claim 1, as amended, requires a cylindrical body having a length defined between a pointed end and a blunt end wherein the cylindrical body is formed by a first element and a second element wherein the first element has a uniform width between the pointed end and the blunt end and further wherein the first element is cross-shaped. On page 10 in the patent application, lines 2-8, Applicant states:

> The introducer 50 may have a pointed end 38 and a blunt end 40. <u>The first element 32 of the introducer is preferably a cross-shaped cylindrical rod 31</u> (emphasis added) with a circular cut 34 from the blunt end 40 to a right angle notch 42. The second element 36 may fit into the circular cut 34 of the first element 32 of the introducer 50.

Independent Claim 12, as amended, requires a flexible hollow body having a length defined between a pointed end and a bottom end wherein the pointed end is closed and further wherein the flexible hollow body is a cylindrical tube having a diameter wherein the bottom end of the flexible hollow body has a width greater than the

diameter and further wherein the flexible hollow body has a plurality of holes defining passageways to deliver the local aesthetic to the tissue of the patient wherein the passageways extend from an interior of the flexible hollow body to an exterior of the flexible hollow body. On pages 7 and 8, lines 30-33 and 1-17, respectively, of the specification, Applicant states:

> The catheter 10 preferably has a pointed end 100 and a bottom end 104. The bottom end 104 of the cylindrical tube 102 preferably has a width greater than the diameter of the cylindrical tube 102. A notch 106 may be located near the pointed end 100, and a second notch 108 may be located near the bottom end 104. The cylindrical tube 102 may be constructed of a porous material 110, or alternatively, with a plurality of holes 112 throughout its length. In an embodiment, the catheter 10 may be used, for example, during cardiac surgery to deliver a local anesthetic directly to nerves of a sternum of a patient. Or, for example, the catheter 10 may be used by a paramedic to deliver local anesthetic to the knee of an injured person prior to transporting the person to a hospital.

Contrary to the assertions of the Patent Office, Applicant had possession of the claimed invention as defined in Claims 1-3, 5, 6 and 12 by describing the claimed invention with all of its limitations using descriptive means, such as, words, structures and figures that fully set forth the claimed invention. Clearly, FIG. 1 illustrates a flexible hollow body 10 having a length defined between a top end 100 and a bottom end 104 wherein the top end 100 is closed as required by independent Claim 1. Further, FIG. 5 illustrates a cylindrical body 50 having a length defined between a first end 38 and a second end 40 wherein the first end 38 is

pointed and further wherein the second end 40 is flat as required by Claim 1. Still further, FIG. 5 illustrates a cylindrical body 50 which is formed by a first part 36 and a second part 32 wherein the first part 36 has a length defined between the first end 38 and the second end 40 wherein the first part 36 has a uniform width between the first end 38 and the second end 40 and further wherein the second part 32 forms a cross at a distance from the second end 40 as required by Claim 1. Moreover, FIG. 1 illustrates a flexible hollow body 10 having a length defined between a pointed end 100 and a bottom end 104 wherein the pointed end 100 is closed as required by Claim 12.

Nonetheless, Applicant amended Claims 1-3, 5, 6 and 12 to clarify the claimed invention as described in the present patent application and to expedite the application to issue. Therefore, Applicant asserts that the amendments to Claims 1-3, 5, 6 and 12 overcome the objections under 35 U.S.C. §112, first paragraph. Notice to that effect is requested.

With respect to the rejection of Claims 1-6, 12-14, 21 and 22 under 35 U.S.C. §103(a) as being obvious over *Ginn* in view of *Yarger*, Applicant submits that this rejection has been overcome by the amendment to Claims 1 and 12 and for the reasons that follow.

In the Office Action, the Patent Office asserts:

> *Ginn* teaches a catheter introducer device comprising of a cylindrical body defining a cross with a length defined between a pointed end 26 and a flat end 30. A first part 24 and a second part 22, wherein the first and

> the second part defines the cylindrical body. Locking mechanism (figs 6-7) where the first part and the removable second part are locked together. The pointed end of the cylindrical body gradually tapers to the cylindrical portions. A recess portion 40 along the length of the first portion 22 and a protruding element 42 defined in shape by a right angle located along the recessed portion of the first part. The recess portion 40 may readily accept the protrusion 42 along the length of the removable second part. A first hole 78 located a distance from the pointed end of the cylinder. A leg 66 attached to the bottom end of the cylinder. A second hole 70 located on the leg of the cylinder and a thread connected (locking mechanism) 80 and 74 to the cylinder form the second hole to the first hole. A groove or plurality of holes 38 cut into the cylinder. *Ginn* does not teach a catheter with two notches located a distance from each other.
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> *Yarger* teaches a catheter (tube) with two notches 28a a distance from each other with a locking mechanism 24 located on the bottom end of the flexible body. The tube also comprises of multiple holes 28b.

As discussed above, independent Claim 1, as amended, requires a flexible hollow body having a length defined between a pointed end and a bottom end. Further, Claim 1 requires a cylindrical body having a first element which is cross-shaped wherein the pointed end of the flexible hollow body is removably attached to the first element of the cylindrical body wherein the first notch of the flexible hollow body secures to the pointed end of the first element.

Independent Claim 12, as amended, requires a flexible hollow body having a length defined between a pointed end and a bottom end wherein the flexible hollow body has a plurality of holes defining passageways to deliver the local aesthetic to the tissue of the patient wherein the passageways extend from an interior of the

flexible hollow body to an exterior of the flexible hollow body. Further, Claim 12 requires a notch located on the flexible hollow body at a distance between the pointed end and the plurality of holes wherein the notch is pulled inward with respect to the skin of the patient to place the flexible hollow body in the tissue of the patient and further wherein the pointed end and the bottom end of the flexible hollow body extend outward with respect to the skin of the patient.

Contrary to the assertions of the Patent Office, *Ginn* merely teaches a slat assembly for harvesting vascular conduits or vessels. The slat assembly taught by *Ginn* has two arcuate slats which are laterally translatable relative to each other. The two slats have similar cross-sections across their width dimensions. To enable the lateral translation of the assembly, a series of slots is formed in one of the slats, and a corresponding series of pins is secured to the other slat with each pin being slidably contained by a corresponding slot. Furthermore, *Ginn* teaches that "to vary the width dimension of the slide assembly, the upper slat is provided with a series of spaced, identical slots which, in this embodiment, extend diagonally at a selected angle across a major portion of the slat's width."

Yarger merely teaches a suction tube for removing fluid from a body cavity, viscus or wound. The tube has an elongate tubular section with an exterior surface and an interior surface defining

an internal longitudinal passageway. The tube has a proximal end portion designed to be connected to a suction source and a distal end portion designed to be inserted into a body cavity, viscus or wound. The tubular section includes a plurality of radially extending, circumferentially spaced elongated portions extending along the length of the tubular section. Further, *Yarger* merely teaches a plurality of spaced holes that extend transversely through the tubular body coupling the region surrounding the tubular body with the internal longitudinal passageway.

Clearly, neither *Ginn* nor *Yarger*, taken singly or in combination, teaches or suggests a flexible hollow body having a length defined between a pointed end and a bottom end as required by Claim 1. The Patent Office admits that "*Ginn* does not teach a catheter with two notches located a distance from each other." Yarger merely teaches that "the distal tip end 31 of the tubular section 22 is shown as rounded and sealed in the embodiment in FIGS. 1 and 2." Therefore, neither *Ginn* nor *Yarger*, taken singly or in combination, teaches or suggests a flexible hollow body having a length defined between a pointed end and a bottom end as required by Claim 1.

Further, neither *Ginn* nor *Yarger*, taken singly or in combination, teaches or suggests a first element which is cross-shaped wherein the pointed end of the flexible hollow body is removably attached to the first element of the cylindrical body

flexible hollow body to an exterior of the flexible hollow body. Further, Claim 12 requires a notch located on the flexible hollow body at a distance between the pointed end and the plurality of holes wherein the notch is pulled inward with respect to the skin of the patient to place the flexible hollow body in the tissue of the patient and further wherein the pointed end and the bottom end of the flexible hollow body extend outward with respect to the skin of the patient.

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an internal longitudinal passageway. The tube has a proximal end portion designed to be connected to a suction source and a distal end portion designed to be inserted into a body cavity, viscus or wound. The tubular section includes a plurality of radially extending, circumferentially spaced elongated portions extending along the length of the tubular section. Further, *Yarger* merely teaches a plurality of spaced holes that extend transversely through the tubular body coupling the region surrounding the tubular body with the internal longitudinal passageway.

Clearly, neither *Ginn* nor *Yarger*, taken singly or in combination, teaches or suggests a flexible hollow body having a length defined between a pointed end and a bottom end as required by Claim 1. The Patent Office admits that "*Ginn* does not teach a catheter with two notches located a distance from each other." Yarger merely teaches that "the distal tip end 31 of the tubular section 22 is shown as rounded and sealed in the embodiment in FIGS. 1 and 2." Therefore, neither *Ginn* nor *Yarger*, taken singly or in combination, teaches or suggests a flexible hollow body having a length defined between a pointed end and a bottom end as required by Claim 1.

Further, neither *Ginn* nor *Yarger*, taken singly or in combination, teaches or suggests a first element which is cross-shaped wherein the pointed end of the flexible hollow body is removably attached to the first element of the cylindrical body

wherein the first notch of the flexible hollow body secures to the pointed end of the first element as required by Claim 1. *Ginn* merely teaches that "a series of slots are formed in one of the slats and a corresponding series of pins are secured to the other slat with each pin being slidably contained by a corresponding slot." The Patent Office admits that "*Ginn* does not teach a catheter with two notches located a distance from each other." Further, *Yarger* merely teaches that "tubular section 22 includes a plurality of spaced apart transverse holes, generally designated as 28, coupling the hollow interior (longitudinal bore) 30 of the tubular section 22 with the region surrounding the tubular section." Clearly, nowhere do *Ginn* or *Yarger*, taken singly or in combination, teach or suggest a cylindrical body having a first element which is cross-shaped wherein the pointed end of the flexible hollow body is removably attached to the first element of the cylindrical body wherein the first notch of the flexible hollow body secures to the pointed end of the first element as required by Claim 1.

Neither *Ginn* nor *Yarger*, taken singly or in combination, teaches or suggests a flexible hollow body having a plurality of holes defining passageways to deliver the local aesthetic to the tissue of the patient wherein the passageways extend from an interior of the flexible hollow body to an exterior of the flexible hollow body as required by Claim 12. Further, neither *Ginn* nor

Yarger, taken singly or in combination, teaches or suggests a notch located on the flexible hollow body at a distance between the pointed end and the plurality of holes wherein the notch is pulled inward with respect to the skin of the patient to place the flexible hollow body in the tissue of the patient and further wherein the pointed end and the bottom end of the flexible hollow body extend outward with respect to the skin of the patient as required by Claim 12.

The Patent Office admits that "*Ginn* does not teach a catheter with two notches located a distance from each other." *Yarger* teaches that "the distal tip end 31 of the tubular section 22 is shown as rounded and sealed in the embodiment in FIGS. 1 and 2." Further, *Yarger* teaches that "a sump suction tube assembly 20 includes a perforated, elongate tubular section 22 designed to be inserted into the body, for example, through the nose, down the throat, and into a hollow viscus, e.g., the stomach, for removing fluids therefrom, for instance, if the patient's intestines are not functioning properly." Still further, *Yarger* teaches that "body fluid may be drawn into the interior 30 of the tubular section 22 directly through holes 28 by a vacuum source (not shown) coupled with connector 24." Moreover, *Yarger* teaches that "typically, the vacuum source is a combination suction and drainage collection device." Furthermore, *Yarger* teaches that "while the present invention has been described in terms of a nasogastric suction

tube, a body cavity suction tube and a wound drainage tube, it is contemplated herein that the tubes may be used in any body cavity, viscus, wound, or surgical site where removal of fluids, whether liquid or gas, is desired."

Nowhere does *Yarger* teach or suggest a flexible hollow body having a length defined between a pointed end and a bottom end wherein the flexible hollow body has a plurality of holes defining passageways to deliver the local aesthetic to the tissue of the patient wherein the passageways extend from an interior of the flexible hollow body to an exterior of the flexible hollow body as required by Claim 12. Further, nowhere does *Yarger* teach or suggest a notch located on the flexible hollow body at a distance between the pointed end and the plurality of holes wherein the notch is pulled inward with respect to the skin of the patient to place the flexible hollow body in the tissue of the patient and further wherein the pointed end and the bottom end of the flexible hollow body extend outward with respect to the skin of the patient as required by Claim 12. Therefore, neither *Ginn* nor *Yarger*, taken singly or in combination, teaches or suggests a flexible hollow body having a length defined between a pointed end and a bottom end wherein the flexible hollow body has a plurality of holes defining passageways to deliver the local aesthetic to the tissue of the patient wherein the passageways extend from an interior of the flexible hollow body to an exterior of the flexible hollow body as

required by Claim 12. Moreover, neither *Ginn* nor *Yarger*, taken singly or in combination, teaches or suggests a notch located on the flexible hollow body at a distance between the pointed end and the plurality of holes wherein the notch is pulled inward with respect to the skin of the patient to place the flexible hollow body in the tissue of the patient and further wherein the pointed end and the bottom end of the flexible hollow body extend outward with respect to the skin of the patient as required by Claim 12.

Moreover, a person of ordinary skill in the art would never have been motivated to combine *Ginn* and *Yarger* in the manner suggested by the Patent Office in formulating the rejection under 35 U.S.C. §103(a). More specifically, Applicant submits that the Patent Office is merely "piece-mealing" references together, providing various teachings and positively defined limitations of Applicant's catheter assembly to deprecate the claimed invention. Of course, hindsight reconstruction of Applicant's invention is impermissible. Applicant respectfully submits that Claims 1 and 12 distinctly define the present invention from *Ginn* and *Yarger,* taken singly or in combination.

It is submitted that the question under §103 is whether the totality of the art would collectively suggest the claimed invention to one of ordinary skill in this art. In re Simon, 461 F.2d 1387, 174 USPQ 114 (CCPA 1972).

That elements, even distinguishing elements, are disclosed in

the art is alone insufficient. It is common to find elements somewhere in the art. Moreover, most if not all elements perform their ordained and expected functions. The test is whether the invention as a whole, in light of all of the teachings of the references in their entireties, would have been obvious to one of ordinary skill in the art at the time the invention was made. Connell v. Sears, Roebuck & Co., 722 F.2d 1542, 220 USPQ 193 (Fed. Cir. 1983).

It is insufficient that the art disclosed components of Applicant's invention, either separately or used in other combinations. A teaching, suggestion, or incentive must exist to make the combination made by Applicant. Interconnect Planning Corp. v. Feil, 774 F.2d 1132, 1143, 227 USPQ 543, 551 (Fed. Cir. 1988).

With the analysis of the deficiencies of the *Ginn* and *Yarger* patents in mind, as enumerated above, no reason or suggestion in the evidence of record exists why one of ordinary skill in the art would have been led to modify *Ginn* with *Yarger* to produce the claimed invention. Therefore, *prima facie* obviousness has not been established by the Patent Office as required under 35 U.S.C. §103.

Even assuming that one having ordinary skill in the art could somehow have combined the references applied by the Patent Office, the references still lack the novel features and structural relationships positively recited in Claims 1 and 12. Namely,

neither *Ginn* nor *Yarger*, taken singly or in combination, teaches or suggests a flexible hollow body having a length defined between a pointed end and a bottom end as required by Claim 1. Further, neither *Ginn* nor *Yarger*, taken singly or in combination, teaches or suggests a first element which is cross-shaped wherein the pointed end of the flexible hollow body is removably attached to the first element of the cylindrical body wherein the first notch of the flexible hollow body secures to the pointed end of the first element as required by Claim 1.

Neither *Ginn* nor *Yarger*, taken singly or in combination, teaches or suggests a flexible hollow body having a length defined between a pointed end and a bottom end wherein the flexible hollow body has a plurality of holes defining passageways to deliver the local aesthetic to the tissue of the patient wherein the passageways extend from an interior of the flexible hollow body to an exterior of the flexible hollow body as required by Claim 12. Further, neither *Ginn* nor *Yarger*, taken singly or in combination, teaches or suggests a notch located on the flexible hollow body at a distance between the pointed end and the plurality of holes wherein the notch is pulled inward with respect to the skin of the patient to place the flexible hollow body in the tissue of the patient and further wherein the pointed end and the bottom end of the flexible hollow body extend outward with respect to the skin of the patient as required by Claim 12. Accordingly, the rejection of

Claims 1 and 12 under 35 U.S.C. §103(a) has been overcome and should be withdrawn. Notice to that effect is requested.

Further, Claims 2-6, 21 and 22 depend from independent Claim 1; and Claims 13 and 14 depend from independent Claim 12. These claims are also believed allowable over the references of record for the same reasons set forth with respect to their parent claims since each sets forth additional structural elements of Applicant's catheter assembly and catheter, respectively. Notice to that effect is requested.

In view of the foregoing amendments and remarks, Applicant respectfully submits that all of the claims in the application are in allowable form and that the application is now in condition for allowance. If, however, any outstanding issues remain, Applicant urges the Patent Office to telephone Applicant's attorney so that the same may be resolved and the application expedited to issue. Applicant requests the Patent Office to indicate all claims as allowable and to pass the application to issue.

Respectfully submitted,

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